(Submitted via Internet on November 14, 2001)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Tall Oil and Related Substances.

The Pine Chemicals Association (PCA) proposes that Tall Oil and six other related chemicals be considered a category for the HPV Challenge Program. We agree with this proposal with one exception, namely tall oil pitch, which may well have a considerably different composition and biological properties than the others. Accordingly, this compound should be tested separately (except to any extent existing data on this compound obviates the need for such testing). Specific comments are as follows:

1. We recognize that tall oil and its analogs are complex mixtures comprised primarily of rosin, fatty acids, terpenes and sterols. We also recognize that the composition is variable, depending on a number of factors including climate and soil conditions. Nevertheless, we agree that six of the proposed members (other than tall oil pitch) are sufficiently similar in structure and relevant chemical and biological factors to justify placing them in a category.

2. Tall oil pitch is a semi-solid material that is the residue remaining after distillation of tall oil. Thus, its composition might be quite different than distilled tall oil, which is the member of the category proposed for testing by the PCA. Moreover, tall oil pitch is used in a much different way than tall oil in that is burned as a fuel and would likely produce numerous other potentially toxic chemicals as a consequence of the burning process. Although tall oil pitch is also highly variable in composition, it seems that some reasonable sample could be chemically analyzed and then used for testing. We recommend genetic toxicity tests and a combined repeat dose/reproduction and development study for tall oil pitch. Acute toxicity testing is not necessary.

3. We agree with the proposal to test distilled tall oil in ecological and repeat dose/reproduction and development studies, as no data is available on these endpoints for members of the proposed category.

4. We agree that no further acute toxicity tests in rodents are needed, as these mixtures possess very low acute toxicity.

5. We agree with the proposal to test distilled tall oil for genetic toxicity.

6. The chemical structures of many of the chemicals found in tall oil suggest the possibility of estrogenic activity. We recognize that estrogenic-activity screening is not included within the Screening Information Data Set under the High Production Volume Initiative. Nonetheless, given the scientific and public health concern regarding endocrine disrupting chemicals in our environment, we believe that the PCA should consider testing tall oil and tall oil pitch for estrogenic activity in a simple screening assay such as the MCF cells or another estrogen responsive cell type. We regard such testing as a high priority for post-HPV work on this

chemical (this does not imply that such testing should await completion of the HPV work).

Finally, we also wish to raise a point that goes beyond the specific test plan for tall oil and related chemicals. We strongly support the use of chemical categories for the HPV testing program, both in general and as applied to tall oil and related chemicals (other than tall oil pitch as noted above). Such an approach provides the needed toxicological data in a timely, cost-effective way and reduces the use of animals in toxicity testing. However, categories are often difficult to establish in a scientifically credible way. We believe that the use of microarray technologies to assess patterns of gene expression after exposure of various cell types to members of a proposed class could significantly increase our confidence in establishing categories. This is especially true for complex mixtures such as tall oil and many other substances covered under the HPV program. We urge EPA and the sponsoring industries to consider the development of a mutually agreeable gene expression protocol as an efficient tool in efforts to establish appropriate categories under the HPV program.

Thank you for this opportunity to comment.

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